5.1 Submitter's Name, Address, Telephone Number, Contact Person, and Date Summary Prepared

A.	Company Name:	Helix Medical, LLC.
B.	Company Address:	1110 Mark Avenue Carpinteria, CA 93013
C.	Company Phone:	1 (805) 576-5308
D.	Contact Person:	Belinda Jackson Senior Regulatory Affairs Specialist Helix Medical, LLC 1110 Mark Avenue Carpinteria, CA 93013 USA Phone +1 (805) 576-5308 belinda.jackson@helixmedical.com

5.2 Date Summary Prepared

December 16, 2013

5.3 Name of Device, Including Trade Name and Classification Name

A.	Device Trade Name:	Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis
B.	Common Name:	Adjustable Bi-Flanged Fistula Prosthesis
C.	Classification Name(s):	Ear, nose and throat manual surgical instrument
D.	Classification Regulation:	21 CFR 874.4420 Class I
E.	Product Code:	LRC
F.	Advisory Panel:	Ear, Nose, and Throat Devices Branch

5.4 Predicate Devices

The Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis is substantially equivalent to the Montgomery Radiopaque Salivary Bypass Tube, cleared 510(k) K96268, and the Hood Laboratories Salivary Bypass Tube, cleared under K841350, with respect to indications for use, materials and mechanism of action.

5.5 Device Description

The Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis is a bi-flanged silicone device connected with a stretchable (elastomeric) beaded stem. Both flanges are the same diameter for a given size device. The inner flange is flexible enough to allow folding for trans-fistula insertion by a trained physician. The device is fabricated from implant grade silicone.

The product will be offered in three sizes: 25mm, 38mm and 50mm. The size is the outside diameter of the sealing flange. The flange size options allow the device to accommodate the size of the fistula in the tissue. The three (3) sizes offered are to close fistulas of size between approximately 6 mm diameter and 25 mm diameter, and tissue thickness from approximately 1.5mm to 25mm. The flanges, which are flexible, allow the device to conform to the contours of the tissue at the site yet minimize leakage.

The Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis Insertion and Removal Catheter is supplied as an accessory to insert or remove the 25 mm and 38 mm Blom-Singer ® Adjustable Bi-Flanged Fistula Prostheses.

5.6 Indications for Use

The Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis is indicated for the management of hypopharyngeal fistulae. This is a short-term medical device, normally intended for continuous use for not more than 29 days. It needs periodic replacement.

5.7 Comparison of Technological Characteristics

As shown in Table 5.1 below, the Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis has the same indications for use, materials and mechanism of action as the predicate devices (Montgomery Radiopaque Salivary Bypass Tube and Hood Salivary Bypass Tube). The Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis is therefore substantially equivalent to the predicate devices.

Table 5.1: Comparison of Blom-Singer® Bi-Flanged Fistula Prosthesis with Predicate Devices

	Device for Clearance	Predicate Device	Predicate Device
Device Name	Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis	Montgomery Radiopaque Salivary Bypass Tube	Hood Salivary Bypass Tube
510(k) Number	K130736	K962688	K841350
Manufacturer	Helix Medical, LLC	Boston Medical Products	Hood Laboratories
FDA Device Classification	Class I	Class I	Class I
Regulation Number	21 CFR 874.4420	21 CFR 874.4420	21 CFR 874.4420
Product Code	LRC	LRC	ZZZ
Radiopaque	Yes	Yes	No
Intended Use	Management of hypopharyngeal fistulae	Management of esophageal and hypopharyngeal fistula	Control salivary leakage from pharyngocutaneous fistula
Mechanism of action	Directs saliva past fistula keeping fistula dry; allows user to swallow liquids	Directs saliva past fistula keeping fistula dry; allows user to swallow liquids	Directs saliva past fistula keeping fistula dry; allows user to swallow liquids
Duration of contact with tissue	Short term, Less than 29 days	Recommended lifetime 6 months	Depends on surgeon's judgment
Allows eating by mouth and swallowing during time in situ	Yes	Yes	Yes
Method for insertion	Non-Sedated or sedated	Sedated	Sedated
Supplied sterile?	Yes	No, supplied ready for sterilization	No, supplied ready for sterilization
Diameters	25mm, 38mm, 50mm	8mm, 10mm, 12mm, 14mm, 16mm, 18mm, 20mm	8mm, 10mm, 12mm, 14mm, 16mm, 18mm, 20mm
Material	Implant Grade Silicone	Implant Grade Silicone	Medical grade silicone

5.8 Brief Summary of Nonclinical Tests and Results

In accordance with ISO 10993-1:2009, cytotoxicity, sensitization, and irritation testing were performed on the Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis. The device was found to be non-cytotoxic, non-sensitizing, and non-irritating.

Design verification testing demonstrated that the Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis met all performance characteristics established for the device, namely, that the prosthesis closes and seals when placed, adjusted and a snug fit is achieved, the stem does not tear or break when placed and adjusted by a qualified trained medical professional, and the locking loop functions as designed to prevent loss of the proper fit.

The Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis and Insertion and Removal Catheter are both sterilized by gamma radiation. Tables 5.2 and 5.3 below provide

summaries of the sterilization validation test results. The results show that all samples were found to be within the guidelines ANSI/AAMI/ISO 11137-2, Method VDmax25 and sterilization verification was successfully completed.

Table 5.2: Summary of Sterilization Validation Test Results for the Blom-Singer® Bi-Flanged Fistula Prosthesis

Sterilization Characteristic	Value / discussion
Dose Mapping	The verification dose delivered for the samples had a minimum dose of 8.2 kGy and a maximum dose of 8.6 kGy, which did not vary from the calculated verification dose by more than ± 10%, the acceptable range.
Bioburden	Overall average of 32.2 colony forming units (cfu)/device; average bioburden less than 1000 organisms
Verification Dose	8.4 kGy
Sterility Test Results	All samples passed for sterility and therefore the sterilization dose of 25 kGy is the 10^{-6} SAL dose for this product.
Bacteriostasis/Fungistasis	Bacteriostatic or Fungistatic characteristics were not shown to be associated with the sterility cultures of the test article when challenged with *Bacillus subtilis*, ATCC 6633, *Candida Albicans*, ATCC 10231, and *Aspergillus niger*, ATCC 16404.

Table 5.3: Summary of Sterilization Validation Test Results for the Blom-Singer® Bi-Flanged Fistula Prosthesis Insertion and Removal Catheter

Sterilization Characteristic	Value / discussion
Dose Mapping	The verification dose delivered for the samples had a minimum dose of 5.6 kGy and a maximum dose of 6.8 kGy, which did not vary from the calculated verification dose by more than ± 10%, the acceptable range.
Bioburden	Overall average of 4.13 colony forming units (cfu)/device; average bioburden less than 1000 organisms
Verification Dose	6.2 kGy
Sterility Test Results	All samples passed for sterility and therefore the sterilization dose of 25 kGy is the 10^{-6} SAL dose for this product.
Bacteriostasis/Fungistasis	Test results are contingent upon the samples not being Bacteriostatic or Fungistatic as tested. Test article was challenged with *Bacillus subtilis*, ATCC 6633, *Candida Albicans*, ATCC 10231, and *A. brasiliensis*, ATCC 16404.

Accelerated aging testing to support a three (3)-year shelf life for the Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis has been completed. Samples were evaluated for the effects of aging after 1-year, 2-year and 3-year. The product accelerated aging

study tests were successfully completed and passed the acceptance criteria for burst test, dye migration test, and label integrity. Post-accelerated aging study design verification testing was performed and the test results of the samples packaged, sterilized, and accelerated-aged for 1-yr and 3-yr satisfied the acceptance criteria thereby verifying that sterilization and 3-year aging has no detrimental impact to the safety and efficacy of the Blom-Singer® Bi-Flanged Fistula Prosthesis.

Accelerated aging testing to support a three (3)-year shelf life for the Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis Insertion and Removal Catheter has also been completed. One year and three year accelerated aged samples met the Acceptance Criteria: The samples for the time period 1-year and 3-year were inspected and found no signs of deterioration or damage. All burst and dye tested pouches met the acceptance criteria. The following additional tests were also performed on the 1-year and 3-year samples:

- Dimensional Inspection – All samples were within the drawing tolerance allowances and pass.
- Ultimate Tensile Strength Force Test for eyelet – All samples met the pull test requirement of $\geq$ 2.0 pounds.
- Tensile Strength Force Test for eyelet to beaded stem (Placement) – All samples met the pull test requirement of $\geq$ 0.5 pounds.
- Tensile Strength Force Test for eyelet to beaded stem (Removal) – All samples met the pull test requirement of $\geq$ 0.5 pounds.

All the 3 year accelerated aged product samples had been previously used to successfully place and remove fistula devices.

Real Time Aging studies are underway for the Fistula Prosthesis and the Insertion and Removal Catheter.

5.9 Brief Summary of Retrospective Clinical Cases

A retrospective review was conducted of twenty-five (25) patients treated for pharyngo-cutaneous and other similar fistulas at ten (10) institutions with custom-fabricated adjustable bi-flanged fistula prostheses. The custom-fabricated fistula prostheses were manufactured using commercially-available medical grade silicone and are technologically similar to the Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis. The devices are comprised of a single or double silicone stem and two flanges which were sized to meet the specific needs of the patient.

The patients ranged in age from 36-87 years of age and consisted of 15 males and 10 females. The duration the prosthesis remained in place ranged from 2 days to 24 months. Of the 25 patients treated, 21 (84%) were reported to control or eliminate salivary leakage. The size of the fistula decreased in 11 out of 25 (44%) of the patients.

The review of the clinical experience demonstrated that the device provided a safe and effective alternative for managing salivary fistulas. The majority of patients treated using

this modality were able to control or eliminate salivary leakage in the absence of any serious adverse events.

5.10 Substantial Equivalence

On the basis of the same indications for use, materials and mechanism of action as shown in Table 5.1, and the results of the nonclinical tests described in section 5.8, the Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 17, 2013

Helix Medical, LLC
Ms. Belinda Jackson
Senior Regulatory Affairs Specialist
1110 Mark Avenue
Carpinteria, CA 93013-2918

Re: K130736
Trade/Device Name: Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis
Regulation Number: 21 CFR 874.4420
Regulation Name: ENT Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: November 13, 2013
Received: November 15, 2013

Dear Ms. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130736

Device Name: Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis

Indications For Use:
The Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis is indicated for the management of hypopharyngeal fistulae. This is a short term medical device, normally intended for continuous use for not more than 29 days. It needs periodic replacement.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

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